CLAIMS:

What is claimed is

1) An improved, modified method for the production-scale manufacture of large, clinical grade, sterile batches of poly-ICLC, a complex of high molecular weight polyriboinosinic-polyribocytidylic acid; low molecular weight poly-1-lysine; and carboxymethylcellulose, having greater accuracy of drug delivery in clinical applications, and increased biological potency and interferon induction activity in primates, comprising the steps of adding poly-L-lysine component solution very slowly to a carboxymethylcellulose component solution over a period of at least 4 days, and mixing for the entire blending time vigorously enough to form a vortex and minimize precipitate buildup.

2) The method of Claim 1, wherein the viscosity of the carboxymethylcellulose is decreased by warming to about 35°C, but not more than 40°C so as to allow a good vortex while mixing.

3) The method of claim 1 wherein evaporation due to warming is offset by addition of sterile water for injection during the mixing process.

4) The method of claims 1 wherein the polyinosinic acid component solution is clarified by warming to about 35°C prior to sterilization by filtration

5) A method of treatment of disease selected from among the group consisting of malignant brain tumors, melanoma, breast and lung cancer, colon cancer, sarcomas, renal cell cancer, leukemias, lymphomas, microbial infections including influenza, flavivirus infections, West Nile virus, Japanese encephalitis, dengue, yellow fever, coronaviruses such as SARS, filoviruses such as ebola virus, influenza, poxviruses such as vaccinia and smallpox, adenovirus, hepatitis, herpesviruses infections HIV, AIDS, equine encephalitis, foot & mouth virus, bovine respiratory complex, porcine reproductive respiratory syndrome virus, multiple sclerosis, Guillain Barre syndrome, immune neuropathies, vasculitides, and ionizing radiation injury, comprising the steps of: administering Poly-ICLC intranasally, orally, sublingually, intramuscularly, intravenously, transsdermally or topically in at least two doses spaced 4-72 hours apart, where the first dose is in a moderate range (20 to 100 mcg/kg in humans) sufficient to

induce measurable but not excessive levels of serum interferon; and the second, lower dose is in the maximally effective range (10 to 50 mcg/kg in humans) for unblocking and stimulation of certain interferon and dsRNA inducible enzyme systems, including the PKR and 2'5'OAS.

6) The method of Claim 5 wherein the dose cycles are repeated weekly or twice weekly for months to years.

7) A method for enhancing the action and decreasing the toxicity of a vaccine, comprising the steps of administering Poly-ICLC to a subject, and administering the desired vaccine to said subject

8) The method of Claim 7 wherein said vaccine is smallpox vaccine.

9) A method for clinical regulation in patients and animals of genes selected from among the group that encodes genes involved in control of cytokines and growth factors, RNA synthesis, signaling, protein synthesis, cell metabolism and structure, the cytoskeleton, the extracellular matrix, cell transport, and control of the cell cycle and apoptosis; and further consisting of helicase, interferon induced protein (p56), tumor necrosis factor, interferon regulatory factor, matrix metalloproteinase, plasminogen activator, tumor protein p53, fibroblast growth factor, eukaryotic initiation factor 2, actin filament-associated protein, VCAM-1 and others, comprising the steps of preparing poly-ICLC in accordance with the method of any of claims 1-4, and administering an effective dose to a patient in need of treatment, an effective dose being at a level sufficient to stimulate the early innate host dense of said patient (approximately 10-40 micrograms per kg body weight), and repeated at 24-72 hour intervals.

10) The method of claim 9, in which poly-ICLC is administered intranasally to a patient in need of treatment, an effective dose being at a level sufficient to stimulate the early innate host dense of said patient, (approximately 10-40 micrograms per kg body weight), and repeated in 24-72 hours.